

510K SUMMARY

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Trade name of Device:	None (to be produced for multiple private labels)
Common Name:	General Use Sponge (Non-Sterile and Sterile)
Classification Name:	Synthetic Sponge (Non-Sterile and Sterile) (21 CFR 878.4060)

The products to be manufactured by CODI International BV are non-sterile and sterile versions of a nonwoven synthetic sponge that is substantially equivalent to the product currently marketed by Johnson & Johnson Medical, Inc. and known as Nu Gauze and the product currently marketed by Kendall Co. and known as Versalon. The CODI products do not have a different intended use or different technological characteristics than Johnson & Johnson's Nu Gauze or Kendall's Versalon. The CODI products are made of rayon and polyester fibers and will be sterilized by radiation or ethylene oxide methods. The finished products have a pattern similar to traditional cotton gauze, but they are softer and more absorbent. The CODI products also have minimal linting and wound adhesion compared to traditional cotton gauze. It is intended that the CODI products will be used as a dressing and for other general medical and dental purposes for which cotton gauze has traditionally been used.